K111262

MAY 2 3 2012

510 (k) Summary
Olsen Medical Electrosurgical Cables/Adapters

Company Name and Address:

Olsen Medical
3230 Commerce Center Place
Louisville, KY 40211
Phone (502) 772-4280
Fax (502) 772-4282

Date: April 19, 2011

Trade Name: Olsen Medical Electrosurgical Cable/Adapters
Common Name: Monopolar/Bipolar Electrosurgical Cord and Accessory
Classification Name: 21 CFR 878.4400 Electrosurgical Cutting and Coagulation Device and Accesories-Class II
Device Product Code and Panel Code: GEI

Contact Information:

Larry Potts
President
Olsen Medical
3230 Commerce Center Place
Louisville, KY
Telephone (502)772-4269
Facsimile (502)772-4282
Email larryp@olsenmedical.com

Device Description:

The Olsen Medical Electrosurgical Cables/Adapters has been designed as an accessory to various electrosurgical instruments where monopolar/bipolar electrosurgical cutting and coagulation is desired during surgery. Examples of such instruments are; scissors, forceps, dissectors, lap electrodes and handles. The device connects to the high frequency generator on one end and the active instrument on the other end for cutting and coagulation. It is comprised of an insulated cord and a fixed instrument and generator connector on either end as the means of conveying high frequency electrosurgical energy from the generator to the standard electrosurgical instrument during surgery.
The adapter interfaces between the instrument cable and various model of electrosurgical generators to match a proper fit for ESU model output connection.

Statement of Substantial Equivalence:

The **Olsen Medical Olsen Medical Electrosurgical Cables/Adapters** are substantially equivalent to legally marketed devices by Quantum

Instruments (K941908, K942194), Sutter Medizintechnik (K073450), Smith and Nephew (K083528) and Richard Wolf Medical Instruments (K982667) based on the device's similarity to the predicated device in intended use, materials, design, and technological characteristics.

Indications for Use:

The **Olsen Medical Electrosurgical Cables/Adapters** is intended for connecting monopolar/bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency current from the electrosurgical generator to the surgical instrument.

Technological Characteristic:

The Olsen Medical Electrosurgical Cables/Adapters is similar to Olsen Medical pre-amendment devices like the 900 series monopolar cable and adapters and the 800 series bipolar cables and adapters and are designed to withstand a high frequency voltage of 5,000 volts peak. They share similar indication for use and incorporate similar technological characteristic to most legally marketed electrosurgical devices by Quantum Instruments, Sutter Medizintechnik, Valleylab, Conmed, Kirwan, Bovie, Megadyne, Wolf Instruments, Stryker, Smith and Nephew, Codman, Sutter, Pilling Weck and Erbe.

Device Testing:

The new device is technologically the same as the predicate device. Device qualification criteria meet or exceeds the minimum qualification criteria for the predicate device and conforms to applicable ASTM and ISO Standards for biocompatibility of materials. All tests will meet the applicable requirements of AAMI/ANSI/IEC 60601-2-2:2009 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories. The **Olsen Medical Electrosurgical Cables/Adapters** provides safe connection by adapting the generator connectors with the recess sockets appropriately and insulating the exposed terminal to prevent unintended high frequency leakage current.

Conclusion:

Based on the evaluation, testing, dimensional information and intended use information provided, the **Olsen Medical Electrosurgical Cables/Adapters** is substantially equivalent to the predicate devices listed above. Testing demonstrate that these devices are safe, effective and perform as well as the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Olsen Medical
% Nunie Tabermejo
3230 Commerce Center Place
Louisville, Kentucky 40211

MAY 23 2012

Re: K111262
Trade/Device Name: Olsen Medical Electrosurgical Cables/Adapters
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 30, 2012
Received: May 7, 2012

Dear Nunie Tabermejo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111262

Device Name: Olsen Medical Electrosurgical Cables/Adapters

Indications For Use:

The Olsen Medical Electrosurgical Cables/Adapters are intended for connecting monopolar/bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency current from the electrosurgical generator to the surgical instrument.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111262